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UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

In Re Bard IVC Filters Products Liability Litigation	No. MD-15-02641-PHX-DGC
SHERR-UNA BOOKER, an individual, Plaintiff, v. C.R. BARD, INC., a New Jersey corporation and BARD PERIPHERAL VASCULAR, an Arizona corporation, Defendants.	**PLAINTIFF'S ADDITIONAL BRIEFING RE: ADMISSIBILITY OF TOPICS 3, 7 & 8 OF FDA 483 WARNING LETTER ISSUED JULY 13, 2015** (The Honorable David G. Campbell)

Plaintiff respectfully submits further briefing regarding the admissibility of sections 3, 7 and 8 of the FDA's Form 483 Warning Letter ("Warning Letter," attached as Exhibit A) dated July 13, 2015. (*See* Doc 10519). The Warning Letter, specifically Topic 3 "Quality System Regulation Violations at the Tempe, AZ facility and Queensbury, NY facility," is relevant to Plaintiff's claims for three reasons:

1. The G2 complaint files listed in Topics 3(b) and 3(c) in the Warning Letter show that Bard was aware of these complaints and mishandled them while Ms. Booker's filter remained in her. These violations included misreported complaints and a lack of appropriate follow up, which caused the MAUDE database to be inaccurate. As the letter

states, Bard's mishandling of the complaints violated 21 C.F.R. 820.198(a). The implant dates for these misappropriated events go back as far as 2008,[1] and all subsequent injuries were reported to Bard before Ms. Booker's filter failed.

The G2 complaint records printed from Bard's Trackwise database associated with Topic 3(b) are attached hereto as Composite Exhibit B. These complaints – the handling of which were found in violation of a federal regulation – are not only relevant to the time period Ms. Booker had her filter, but they also involve the G2 filter line[2] and report similar injuries (*See* Exhibit A, Topic 3(b) "embolization of detached filter arm," "detached filter limb," "broken filter and surgical intervention"). Moreover, Topic 3(c) discusses violations of 21 C.F.R. 820.198(a) for failing to maintain information about follow up regarding subsequent surgeries like Ms. Booker's second surgery.

2. Bard engaged in a re-review of hundreds of complaints after receiving the Warning Letter.[3] Ms. Booker's complaint file, #665306, was part of this re-review of complaints as a result of the Warning Letter.[4] Notably, the language in Ms. Booker's complaint record matches, verbatim, the language contained in the complaint records of the G2 complaints cited in the Warning Letter which were re-opened and reviewed: "10/20/2105: A retrospective review of this file was conducted on 10/19/15 to determine if good faith efforts were made to obtain information for sections A-F on the MDR 3500A form."[5] In fact, Ms. Booker's complaint was re-opened on the consecutive day between two of the complaints cited in the Warning Letter.[6]

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[1] *See* Exhibit B, Chart of FDA Warning Letter Complaints.

[2] *See* Trial Transcript, 3/22/18, Testimony of Robert Carr, at 1101:5-8 (the Eclipse filter is part of the G2 filter line).

[3] Exhibit C, Deposition testimony of Chad Modra, 12/15/15, at 274:12 – 281:5.

[4] Exhibit D, at BPV-17-01-00206164 (#665306).

[5] Exhibit E, Sherr-Una Booker's Complaint Record Detail Reports, at BPV-17-01-00206164.

[6] Compare Exhibit D, at BPV-17-01-00206164, with Composite Exhibit B, at TW_COMPLAINT_010120 and TW_COMPLAINT_009986; identical language "A retrospective review…".

3. Bard's complaint handling standard operating procedures (SOPs) identified in Topic 3(a), which the FDA found violated 21 C.F.R. 820.198(a), are described as "current" as of July 13, 2015; however, from a review of these documents it is clear they were in place during the seven-year period that Ms. Booker's G2 filter was implanted from June 21, 2010, to July 28, 2014. Specifically, the Standard for Complaint Investigation Process (CQA-STD-55, Rev. 01), which defines the requirements for conducting a complaint investigation, was first drafted on November 8, 2010, and revised in April 28, 2011; the Standard for Complaint Handling (CQA-STD-24, Rev. 11), which defines the requirements for reviewing, receiving, evaluating and investigating complaints, went through several revisions over the years and was last revised on May 23, 2014, one month before her heart surgery; the Standard for Complaint Investigation Activity (SOPQ0153100, Rev. 40), which defines the process by which complaints are handled, appears to be have in place during Ms. Booker's filter placement, although effective dates are not noted on the document; and, the Standard for Complaint Investigations Procedures (SOPQ07000200, Rev. 15), which defines the method for conducting complaint investigations, also appears to be have in place during Ms. Booker's filter placement although effective dates are not noted on the document. Therefore, the procedures for complaint handling that were in violation of 21 C.F.R. 820.198(a) applied to the time period Ms. Booker had her G2 filter.

4. The Warning Letter is evidence of a violation of a federal regulation and thus probative of Plaintiff's punitive damage claim: "Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints as required by 21 C.F.R. 820.198(a)." Though the Warning Letter is dated July 13, 2015, Topic 3 of the letter is relevant to the filter, injury, and time period Ms. Booker had her G2 filter. Under Georgia law, evidence of compliance with federal regulations, including the 510(k) regulations, is relevant to the reasonableness of Bard's conduct and to Plaintiff's punitive damage claims, *see* Doc. 9881, as it is probative of whether a manufacturer has acted with conscious indifference. Moreover, Bard's argument under Fed. R. Evid. 403 is misplaced. In order for

Bard to be unfairly prejudiced the evidence must "substantially outweigh" the probative value. Yet it was Bard's choice not to comply with FDA regulations regarding tracking complaints, regardless of when it was discovered.[7] Bard's primary defense in this case is that its submissions and acts satisfied the FDA,[8] but it now seeks to suppress evidence showing the opposite. In fact, the FDA found Bard's injury reports comprised of risk information misreported, including the exact kind of failures resulting in serious injuries that Ms. Booker experienced. It is Plaintiff that will be unfairly prejudiced if FDA-related evidence is deemed inadmissible when the crux of Bard's case is an FDA-defense of compliance with regulatory processes.

RESPECTFULLY SUBMITTED this 25th day of March, 2018.

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CERTIFICATE OF SERVICE

I hereby certify that on this 25th day of March 2018, I electronically transmitted the attached document to the Clerk's Office using the CM/ECF System for filing and transmittal of a Notice of Electronic Filing.

/s/ Gay Mennuti

[7] *See* Exhibit A, at 1. Inspection date was November 2014.
[8] *See* Trial Transcript, 3/23/18, Testimony of Donna-Bea Tillman, at 1363:1-6 (information provided for the G2 was consistent with FDA's regulatory policy and sufficient to provide risk information based on FDA's expectations).